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510(k) SUMMARY

K052370

DENTSPLY International
World Headquarters
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405-0872

CONTACT: Helen Lewis

DATE PREPARED: August 25, 2005

TRADE OR PROPRIETARY NAME: CP Bracket System

CLASSIFICATION NAME: Orthodontic bracket (872.5470)

PREDICATE DEVICES: Orthodontic Ceramic Brackets (K042178)

DEVICE DESCRIPTION: The CP Brackets are ceramic orthodontic b rackets. These brackets will be used for a complete orthodontic treatment. The brackets are single-use devices.

INTENDED USE: The CP Brackets are indicated for orthodontic movement of teeth.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in the CP Brackets have been used in DENTSPLY's legally marketed devices.

Biocompatibility testing was completed and the results support the safety of the device. A table of the results is included in this submission.

Approximately 20,000 units of this bracket have been sold in Japan since 2003. Only four complaints were received which, upon investigation, were caused by the user failing to follow the adhesive manufacturer's instructions.

We believe that the prior use of the components of the CP Brackets in legally marketed devices, the performance data provided, and the biocompatibility data provided support the safety and effectiveness of the CP Bracket System for the intended uses.

Predicate Device Information:

Predicate Device 510(k) FDA Substantial Equivalence Letter
and Indications for Use Page

Predicate Device Tradename — Mystique® Brackets

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Helen Lewis
Director of Corporate Compliance & Regulatory Affairs
Dentsply International
Susquehanna Commerce Center
221 West Philadelphia Street
York, Pennsylvania 17404-0872

Re: K052370
Trade/Device Name: CP Bracket System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: DYW
Dated: August 25, 2005
Received: August 30, 2005

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

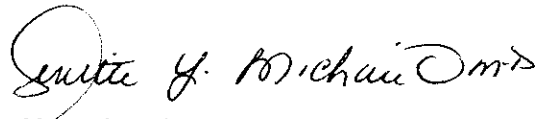
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

(As Required by 21 CFR 807.87(e)

510(K) Number (if known): K052370

Device Name: **CP Bracket System**

Indications for Use:

The CP Bracket System is indicated for orthodontic movement of teeth.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K052370